133

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European Patent Application No. 94928713.0 - 2305
European patent No. 0676937
Title: Intraluminal Graft
Proprietor: Endogad Research PTY Limited

Dear Sirs,

In the name and on behalf of

William Cook Europe ApS
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Zur Kasse

We hereby file opposition against the above-identified patent granted on 17 March 2004. Please find enclosed an order for drawing the opposition fee from our deposit account No. 28030011.

We request the EPO to revoke the patent in full on the grounds of Art. 100(a) EPC, because claims 1 to 10 lack the inventive step required by Art. 52 EPC and Art. 56 EPC, and claim 1 further lack novelty in contradiction to Art. 52 EPC and Art. 54 EPC.

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Fédération Internationale des Conseils en Propriété Industrielle

We enclose the grounds of opposition together with copies of the following documents:

D0: The textbook "Interventional Radiology", Chapter "Expandable Stents", p. 692-699, Georg Thieme Verlag 1990,

D1: The article "Self-Expanding Endovascular Graft: An Experimental Study in Dogs" by Tetsuya Yoshioka et al, AJR 151: p. 673-676 published in October 1988,

D2: EP 0 539 237 A1 published on 28 April 1993,

D3: EP 0 551 179 A1 published on 14 July 1993,

D4: US patent No. 3,304,557 published on 21 February 1967,

D5: WO 92/06734 published on 30 April 1992,

D6: US patent No. 4,130,904 published on 26 December 1978.

D7: Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms" by J.C. Parodi et al., Annals of Vascular Surgery, Volume 5, No. 6, 1991.

In the event that the Opposition Division intends to maintain the patent in full or in amended form oral proceedings are hereby requested.

Yours sincerely,
Internationalt Patent-Bureau A/S

Peter Indahl
(Professional Representative)

Enclosures:
As mentioned
Form 1037

Grounds of opposition

In the following substantiation of the notice of opposition we shall firstly look at the general technical knowledge prior to the priority date, and then look at the invention as described in the opposed patent, and lastly in more detail mention the relevance of the prior art in relation to the claims of the opposed patent. The opposed patent claims the priority date 30 September 1993.

Common general knowledge

The invention in the opposed patent relates to the technical area of intraluminal grafts for use in treatment of aneurysms or occlusive diseases. At the beginning of the nineties, the textbook "Interventional Radiology", Georg Thieme Verlag 1990 was the authoritative textbook on Interventional Radiology and the specific subject of the present invention is the subject of the chapter "Expandable Stents", cf. document D0.

The traditional stent depicted in Fig. 1 on page 692 in D0 is called the "Gianturco-stent" or simply the "expandable metallic stent", cf. the second paragraph in the left hand column on page 692. This stent is constructed of stainless steel wire bent in a zig-zag pattern and encircled to form a cylinder.

An endovascular graft is described on page 696. According to the description in the left hand column on that page, the graft consists of multiple stents in tandem

connected to each other by metallic struts, and a Dacron tubing is wrapped around the outside of the middle group of stents. The lead and trail stents act as anchors for the graft, and the middle stents serve to keep the Dacron tubing open after release from a catheter. The endovascular graft is depicted in Fig. 6, and it clearly appears that that alternate crests of the leading and trailing stents project longitudinally beyond the ends of the Dacron tubing.

The general historical development of the technical area of intraluminal graft implantation is also described in document D7. On page 491 is referenced that the last 50 years of vascular surgery have seen a variety of attempts at curing the serious condition of abdominal aortic aneurysms.

Under the heading "Animal Studies" on page 492 is mentioned that in 1976 intraluminal graft placement began to be explored as a solution to the problem. Thus the technical area at hand is developed by vascular surgeons, who are well aware of the previously used technology.

The graft-stent combination is described on page 493 of D7. The right hand column on that page mentions in the first paragraph that stainless steel were sutured to a thin-walled Dacron graft located so that the graft overlapped one-third of the length of the stent. Consequently, the stents protrude longitudinally beyond the ends of the graft material. This is also depicted in Fig. 10 on page 498 of D7.

The invention in the opposed patent

According to claim 1 of the opposed patent the invention relates to:

a) an intraluminal graft comprising

b) a tubular graft body,

c) which is circumferentially reinforced along its length

d1) by a plurality of

d2) separate,

d3) spaced apart

d4) malleable wires,

e) each of which has a generally closed sinusoidal or zig-zag shape,

f) one of the wires being located adjacent to one end of the graft body, such that

g) alternate crests of the wire project longitudinally beyond said end, and wherein

h) the wires are interwoven with the graft body.

With respect to feature a there is mentioned an intraluminal graft. The expression "intraluminal" does not restrict the manner in which the graft is placed at the desired location. At the beginning of section 0023 is explained that the intraluminal graft in the embodiment depicted in Fig. 1 of the opposed patent is adapted for insertion transfemorally, thus indicating use of the Seldinger endovascular technique, but intraluminal can equally well relate to a graft to be placed within a body lumen by a purely surgical procedure.

With respect to features d1 and d2 the patent descrip-

tion does not disclose that the separate spaced apart wires are not interconnected. A common means of spacing apart two consecutive members is to use a spacer of some kind, which spacer is connected to the spaced apart members. In the present case, the wires to be spaced apart are fixed to a tubular graft body which according to the description in section 0024 can be a crimped tube 16 of woven Dacron. It appears from Fig. 1 of the opposed patent that the crimping extends circumferentially so that the graft is bellow-shaped. As a consequence of this the crimped tube 16 cannot by itself keep apart the spaced-apart wires. The skilled person will consequently not dismiss a solution where some kind of spacers are utilized to keep the wires spaced apart.

Also, it is not disclosed why the wires should be malleable. Malleable being defined as "*metals and other substances that can be beaten or pressed into different shapes easily*" (Oxford Advanced Learners Dictionary) or which are "*yielding, amenable, adaptable*" (Websters).

Stainless steel is the most well-known stent material, and is certainly malleable. Another metal or a plastic are mentioned as other kinds of malleable materials, cf. the description in section 0014.

The spaced apart wires serve two functions, keeping the graft open in the middle area and anchoring the graft to the vascular wall in the end areas.

The anchoring is described in column 2, lines 40-48. Here it is stated that the crests of the wires are

forced into contact with the wall of the vessel and become at least partly embedded into the vessel wall. This caused the effect of anchoring the graft to the vessel wall. The text in the beginning of section 0009 indicates this to be an important feature of the invention.

With respect to feature h it is mentioned at the middle of section 0014 that the wires can be interwoven with the graft body during the production of the graft body when the graft body is of a woven material.

Lacking inventive step

D4 and common general knowledge

It is well-known to the skilled person that there are substantial advantages by stiffening a tubular graft body by mechanical supports extending in the circumferential direction of the tubular graft body and being provided as separate stiffeners placed at longitudinally separated locations on the graft.

Such a graft with stiffeners is described in D4. This graft comprises all the features a) to h) of claim 1 except g).

Thus D4 discloses a graft, viz. a prosthesis requiring support to maintain an open lumen when placed in an animal body, particularly the human body (cf. D4 in column 1, lines 12-15). D4 states that synthetics such as vinyon-N, nylon, Orlon, Dacron, Teflon and Ivalon

have been woven into tubes, for use as arteries, veins, ducts esophagi and the like. Moreover, D4 states in column 1, lines 27-33 that the graft must be flexible because this is essential during an operation when the graft is accommodated in the artery. Another essential feature is that the graft is sufficiently bendable to allow for flexing without collapse and closing of the lumen therein.

In this respect D4 provides a graft in the form of a tube using an association of collagen and a non-absorbable material, wherein the collagen and the non-absorbable material, in the form of a reinforcement are integrated according to a predetermined pattern to provide mechanical support (cf. col. 2 in lines 2-3 and 5). In particular, this is provided in form of a cylindrical tube comprising an association of collagen and a non-absorbable material A having integrated therewith a non-absorbable material B (cf. column 1, lines 63-66).

In particular, it is stated that the term integrated means that the material B is actually incorporated into the structure, as by weaving, such that material B is established as an integral and patterned portion of the tube. Materials A and B can be the same or different. (cf. column 2, lines 6-11.)

As furthermore mentioned in column 3, lines 4-9 and illustrated in particular in Fig. 2, there is provided a woven tube having a main or body portion extending throughout its length with a series of reinforcing ring sections 1, 2, 3, 4 .. spaced along the tube adjacent its outer surface and forming an integral part thereof.

Between the ring sections of the tube there are body sections in which each pick weaves above alternate warp yarns and below intervening warp yarns. Figs. 4-8 show various longitudinal sections of fig 2. In the section of fig. 8, the warp yarn passes over the underlying pick 15 in group 1 and under the overlying pick 16 in that group. This pattern is repeated at spaced intervals of eight warp yarns in the circumferential direction as regards each group and at spaced intervals as between the respective groups in each ring section (cf. column 4 lines 13-20). Thus the reinforcement rings are woven into the tube.

Variations may be made in the weaving pattern in order to integrate a general pattern of reinforcement rings into a tube but adjacent the surface thereof. Examples are made of this stating that instead of an annular ring configuration, the reinforcement can have the form of a helix, alternating ring and helix, double helixes, half-loops, etc. (cf. column 5 lines 60-69). Half-loops being nothing else than a general sinusoidal configuration.

Thus D4 discloses all features of claim 1 lacking only the feature g) that the crest of the wires project longitudinally beyond the end of the graft body. This feature is stated to be an important feature and serves to expand the crests in order to force them into engagement with the vessel wall for anchoring the graft to the wall (cf. section 0011 of the opposed patent.)

However, this feature is common general knowledge of the skilled person certainly knowing of the Gianturco stent and the stent-graft construction described in D0 and above.

D0 describes on page 696 at the middle of the left hand column that the lead and trail stents acted as anchors for the graft, and in Fig. 6b it is clearly seen that the crests of the Gianturco stent extending beyond the end of the graft material are in contact with the wall of the vessel and have become at least partly embedded into the vessel wall.

The skilled person when confronted with the teaching of D4 would have no problem incorporating this into his common general knowledge of D0 and arrive at claim 1.

Claim 1 of the opposed patent consequently does not possess an inventive step over D4

D4 in combination with D1

Also, claim 1 lacks inventive step over the combined teachings of D4 and D1.

Fig. 1 of D1 clearly shows an endovascular stent graft with self-expanding stents and a nylon graft body. The stents are zig-zag shaped and extends beyond the graft body at either end. According to the description under the heading "Material and Methods" on page 673 on D1 the graft is made of three to four stents and a nylon cylinder, and the graft is for placement in the aorta.

D1 clearly indicates that the stent part extending over the graft body has the purpose of holding the graft in place (cf. page 575 last paragraph - page 576 third paragraph), albeit the fact that it is indicated that this holding may be insufficient, and additional barbs may be needed. Such additional barbs however are not an issue of the present invention and they are not excluded by the wording of claim 1.

Thus also D1 presents the skilled person with the teaching necessary for solving the problem of holding the graft of D4, and claim 1 thus lacks an inventive step over this combination.

D4 in combination with D3

Moreover claim 1 lacks an inventive step over the combination of D3 and D4.

D3 discloses a method for repairing an abdominal aortic aneurysm in the abdominal aorta. The method includes the steps of connecting a first tube to a first expandable and deformable tubular member (cf. column 3, lines 44-48). Another feature of the method includes the step of forming the tube of a plurality of expandable and deformable tubular members, each tubular member having a longitudinal axis, by aligning the plurality of tubular members with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart from adjacent tubular members, and embedding the plurality of tubular members

within a layer of deformable and expandable plastic material. (Cf. column 4, lines 31-39.)

It is stated that tubular members 166 could be utilized as a holding means, if they are controllably expanded. (cf. column 10, lines 39-41). In this respect, the leading edge 167 of the tubular member 166 is exposed for direct contact with the aorta. (cf. column 12, line 57 - column 13, line 1.)

As can be seen from Fig. 9, the several tubular members may be interconnected or not.

Thus D3 also presents the skilled person with a solution to the holding of a graft in a vessel. Fig. 10B of D4 show that the projecting portion of the stent include wires running in a zig-zag configuration in the circumferential direction, and the use of such a sinusoidal ring shape is already known from D4. The skilled person has no problem in combining their teachings to arrive at the solution in claim 1 to the holding problem.

D4 in combination with D2

Finally, claim 1 also lacks inventive step over the combination of D2 and D4.

Claim 1 of the contested patent comprises a plurality of stents, viz. at least two. It is not restricted to having any stents between the two stents at either end.

The stents at the ends have alternate crests of the wire, which project longitudinally beyond said end.

D2 discloses a graft having one or more stents. The stents occupy the lumen of the graft, and the stents expand the graft and fit it in position (cf. column 15, line 57 - column 16, line 1).

At least at either end the stents comprise zig-zag shaped spring assemblies in the form of closed rings, made of fine gauge stainless steel wire (cf. Column 7, lines 20-23.)

D2 thus discloses all the features of claim 1, except the feature that the wires are interwoven with the graft body. Instead the spring assemblies are secured to he graft by means of a non-biodegradeable thread (cf. column 7, lines 36-38).

D2 furthermore notes that it not of importance whether the spring assemblies are interconnected or not (cf. column 8, lines 30-42).

Thus starting form D2 the problem can be seen as finding an alternative way of securing the spring assemblies to the graft.

The solution to this problem is clearly presented in D4 teaching that the spring segments, viz. the rings, may be interwoven with the graft body.

The skilled person would have no problems incorporating this teaching into the graft of D2, and claim 1 thus lacks an inventive step.

Lacking novelty over D2

As just explained D2 discloses all the features of claim 1, except the feature that the wires are interwoven with the graft body, if the term interwoven is understood as a true weaving in the sense of weaving a fabric.

However, section 0015 of the opposed patent states that in alternative embodiments the wires may be held in place by sutures. The word interwoven in claim 1 can thus be understood as a kind of connection where the wires are connected with sutures. Given this meaning claim 1 lacks novelty over D2. D2 mentions that the spring assemblies are secured to he graft by means of a non-biodegradeable thread (cf. column 7, lines 36-38).

Claims 2 and 8

Claim 2 has the additional feature that flaps of graft material are provided on the outer side of each crest and protrude longitudinally with each crest beyond the graft body.

In as far as claim 2 can be understood from the feeble support in the description, overlapping flaps are provided overlapping partially the crests at the end. From the figures, these flaps appear occur due to longitudi-

nal incisions in the graft body, referred to as scalloped in claim 8. Notwithstanding the uncertainty as to whether the flaps are part of the graft body or not, providing such incisions in order to allow the crests to flare out is a common design measure readily available to the skilled person.

The skilled person is namely aware that malforming and occlusion in a vessel can be provoked by loose parts hanging into the blood flow in the vessel. In order to avoid this problem he will shape the graft material at the end to follow the contour of the wire, viz. to end at a constant distance from the wire, and this can be obtained by making cut outs in the loose material present in-between the exposed crests of the wire.

Claims 2 and 8 thus involve no inventive step, as this feature would be obvious to the skilled person.

Claim 3

Claim 3 has the additional feature that one wire has a greater amplitude than the next adjacent wire.

This feature is at best unclear, as it most certainly involves the compression state of the stent. Thus for a bulging stent of identical segments compressed at the ends, this would certainly be the case. Such a bulging stent can be seen in fig. 1 of D7.

Nonetheless, as can be seen from Fig. 6 of D0 this feature is common general knowledge. In D0 the upper cau-

dal stent segment is in the relaxed state of the graft extended more widely than the lower stent segment, because they are covered to a different degree by the graft body. This is a simple design consequence of the fact that in the caudal part of the aorta needs more force to counteract the large pulsating blood pressure. Downstream, which is also down in the figure, the pressure is lower, and less force is needed.

Claim 3 is consequently obvious to the skilled person.

Claim 4

Claim 4 adds the feature that one wire has a greater amplitude than the next two adjacent wires.

Following the argumentation above in relation to claim 3 this feature is also anticipated by a bulging stent, and thus not inventive.

Claim 5

Claim 5 is directed to the feature that the wire next to the end of the stent and the next two wires are more closely spaced than the wire intermediate the ends of the graft body.

In D4 the stiffeners near the end is more closely spaced than at the middle of the graft. This clearly appears form Figs. 2 and 4.

Claim 5 is consequently obvious to the skilled person.

Claim 6

Claim 6 indicates that the wavelength of the wires is substantially constant along the length of the graft body when the graft is in a compressed state.

This feature is anticipated by any stent comprised of identical stent segments, or at least segments with the same number of zig-zags.

Such a stent is known form D5. The fact that the stent segments are partially interconnected is not of importance. Rather, this is a simple optional feature that the skilled person would choose to incorporate or not as already indicated above in connection with D2 (cf. D2 column 8, lines 30-34).

Thus this feature is also obvious to the skilled person.

Claim 7

Claim 7 adds the feature that one wire has a greater amplitude and a smaller wavelength than at least a majority of the other wires in the graft, when the graft is in a radially expanded state.

This is closely linked to the bulging of the stent when placed in an aneurysm, where the end parts are restricted by the vessel. The feature in fact only indicates that the graft body has some radial flexibility, so that when the stent is expanded by means of a balloon, the middle segments are allowed to expand more

than those at the end, as they are not restricted by the vessel wall. Such radial flexibility would be available from woven materials as mentioned in D4 or D6.

Claim 9

Claim 9 indicates that the ends of each wire are twisted together. After having threaded the wire through the graft body, it is naturally required to twist the ends together on the outside, where they are readily accessible, rather than on the inside.

Claim 9 is consequently obvious to the skilled person.

Claim 10

Finally, claim 10 adds the feature that the opposite ends of the graft body are provided with a wire which has alternate crests extending longitudinally beyond that end of the graft body.

This feature is commonplace in grafts, and can be found in all of D0, D1 and D2.

Conclusion

Thus, as demonstrated above, all of claims 1 to 10 of the contested patent lack inventive step, and a revocation in full is requested.